

SIGNATURE CARE CHILDRENS IBUPROFEN- ibuprofen tablet, chewable Safeway

Better Living Brands LLC Children's Ibuprofen Drug Facts

Active ingredient (in each chewable tablet)

Ibuprofen 100 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if your child:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- takes more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more

than directed or for longer than directed.

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

Do not use

- if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or had a stroke
- child has asthma
- child is taking a diuretic

Ask a doctor or pharmacist before use if the child is

- under a doctor's care for any serious condition
- taking any other drug

When using this product

- mouth or throat burning may occur; give with food or water
- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- child experiences any of the following signs of stomach bleeding:
 - feels faint
 - vomits blood
 - has bloody or black stools
 - has stomach pain that does not get better
- child has symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- the child does not get any relief within first day (24 hours) of treatment

- fever or pain gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

Other information

- phenylketonurics: contains phenylalanine 6 mg per tablet
- store between 20-25°C (68-77°F)

do not use if printed seal under cap is broken or missing

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **chew or crush tablets completely before swallowing**
- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- if needed, repeat dose every **6-8 hours**
- do not use more than **4 times a day**

Dosing Chart		
Weight (lb)	Age (yr)	Tablets
under 24	under 2	ask a doctor
24-35	2-3	1
36-47	4-5	1 ½
48-59	6-8	2
60-71	9-10	2 ½
72-95	11	3

Inactive ingredients

acesulfame potassium, ammonium glycyrrhizin, aspartame, carnauba wax, croscarmellose sodium, D&C red no. 27 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

Questions or comments?

1-888-723-3929

Package/Label Principal Display Panel

Compare to Children's Motrin® active ingredient

FOR AGES 2 TO 11 YEARS

Children's Ibuprofen

Quality Guaranteed

Chewable Tablets 100 mg

Pain Reliever/Fever Reducer (NSAID)

Chew or crush tablets completely before swallowing

Actual Size

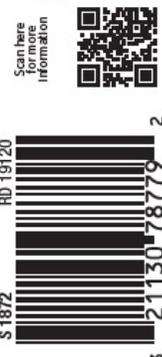
GRAPE FLAVOR

Chewables

Lasts up to 8 hours

GLUTEN FREE

24 CHEWABLE TABLETS



Important: Read all product information before using. Keep this box for important information. This is a tablet for children only.

Drug Facts
Active ingredient (in each chewable tablet) **Purposes**
Ibuprofen (100 mg NSAID)*.....Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses temporarily: ■ reduce fever
■ relieve minor aches and pains due to the common cold, flu, sore throat, headaches, and toothaches.

Warnings
Allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
■ hives ■ facial swelling ■ asthma (wheezing)
■ stomach pain ■ difficulty breathing
If an allergic reaction occurs, stop use and seek medical help right away. Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you child:
■ has had stomach ulcers or bleeding problems
■ takes a blood thinning (anticoagulant) or steroid drug
■ takes other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
■ takes more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher in you use more than directed or for longer than directed. Some heart warnings: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

Drug Facts (continued)
Do not use
■ if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
■ right before or after heart surgery
Ask a doctor before use if
■ stomach/bleeding warning applies to your child
■ child has a history of stomach problems, such as heartburn
■ child has problems or serious side effects from taking pain relievers or fever reducers
■ child has not been drinking fluids
■ child has had a lot of fluid due to vomiting or diarrhea
■ child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or had a stroke
■ child has asthma
■ child is taking a diuretic
■ under a doctor's care for any serious condition
■ taking any other drug

When using this product
■ avoid or throat burning may occur, give with food or water
■ take with food or milk if stomach upset occurs
Stop use and ask a doctor if
■ child experiences any of the following signs of stomach/bleeding:
■ feels faint ■ vomits blood ■ has bloody or black stools
■ has stomach pain that does not get better
■ child has symptoms of heart problems or stroke:
■ chest pain ■ trouble breathing
■ weakness in one part or side of body
■ slurred speech ■ leg swelling

Other information (continued)
■ do not use if printed seal is under cap is broken or missing
■ store between 20°-25° (68°-77°)
■ keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Drug Facts (continued)
Directions
■ chew or crush tablets completely before swallowing
■ this product does not contain dextrose or complete warnings for adult use
■ do not give more than directed
■ first right dose on chart below. If possible, use weight to dose; otherwise use age.
■ if needed, repeat dose every 6-8 hours
■ do not use more than 4 times a day

Dosing Chart

Weight (lb)	Age (yr)	Tablets
under 24	under 2	ask a doctor
24-35	2-3	1
36-47	4-5	1½
48-59	6-8	2
60-71	9-10	2½
72-95	11	3

Questions or comments? 1-888-723-9229
This product is not manufactured or distributed by Johnson & Johnson. Consult your pharmacist or doctor for more information.
DISTRIBUTED BY: BETTER LIVING GERMANYS LLC
PO, BOX 999, PLEASANTON, CA 94596-0099
OUR PHONE NUMBER: 1-888-723-9229
OUR WEBSITE: WWW.BETTERLIVINGGERMANY.COM
OUR ADDRESS: 1177 & 575 FACILITY
0% GUARANTEE ON YOUR MONEY BACK

Compare to Children's Motrin® active ingredient* NDC 21130-701-62

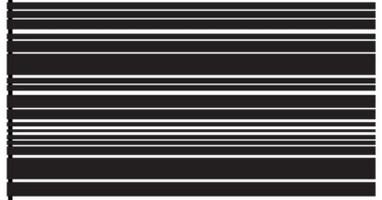
FOR AGES 2 TO 11 YEARS Children's

Ibuprofen

Chewable Tablets 100 mg Pain Reliever/Fever Reducer (NSAID)
Chew or crush tablets completely before swallowing

GRAPE FLAVOR Actual Size
 ■ Chewables
 ■ Lasts up to 8 hours
 ■ GLUTEN FREE

24 CHEWABLE TABLETS



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-701
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	100 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ASPARTAME (UNII: Z0H242BBR1)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUCCINIC ACID (UNII: AB6MNQ6J6L)	

Product Characteristics

Color	PURPLE (Lavender)	Score	2 pieces
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	L521
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-701-62	1 in 1 CARTON	06/10/2019	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA076359	06/10/2019	
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Labeler - Safeway (009137209)

Revised: 11/2022

Safeway